Sheffield Laboratories, Div. Faria Ltd
World's First Toothpaste Manufacturer, Est. 1850

AUG 2 2000

K001077

510(k) Summary

Applicant: Sheffield Laboratories, Div. of Faria Ltd.
170 Broad Street
New London, CT 06320 USA
Phone: (860) 442-4451
Fax: (860) 442-0356
Contact: Kathleen Hacku
Date: March 27, 2000

Device:

- Trade Name: *Lubrigel* Personal Lubricant
- Common name: Personal Lubricant
- Classification name: Lubricant, Patient (per 21 CFR section 880.6375)

Information supporting claims of substantial equivalence, as defined under the Federal Food Drug and Cosmetic Act, with respect to safety and effectiveness is summarized below. For the convenience of the reviewer, this summary is formatted in accordance with the Agency's final rule, "510(k) Summaries and 510(k) Statements" (21CFR807).

New Device's Name: Sheffields's *LubriGel* Personal Lubricant
Predicated Devices(s): K-Y Jelly Personel Lubricant, Ortho-McNeil Pharmaceuticals, Inc., K955648
ASTROGLIDE Personal Lubricant, BioFilm Inc., K935291

Intended Use:

"Sheffield's *LubriGel* Personal Lubricant" is an over-the-counter personal lubricant, specially formulated to lubricate condoms, provide vaginal moisture, and ease the insertion of rectal thermometers, enemas, douches and tampons.

Device Description:

LubriGel Personal Lubricant formula is clear, colorless, odorless, non-sticky, non-greasy, non-irritating personal lubricant. It is a water soluble clear, high viscosity gel-like liquid. Because it is water-soluble, *LubriGel*

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is easily rinsed off with water. The product is packaged in a convenient laminate tube with a flip top cap.

Technological Characteristics:

LubriGel contains only United States Pharmacopeia (USP) or National Formulary (NF) of: Carboxymethy Cellulose, Citric Acid, Methylparaben, Natural Glycerin, Propylparaben and Purified Water.

Summary of Technological Characteristics:

The table below compares the technological characteristics of Sheffield's *LubriGel* to the predicated devices K-Y Brand Liquid Personal Lubricant and ASTROGLIDE.

Feature	*LubiGel*	K-Y Jelly	ASTROGLIDE
Manufacture	Sheffield Laboratories, Div. Faria Ltd.	Ortho-McNeil Pharmaceutical, Inc.,	BioFilm, Inc
Contains purified water	yes	yes	yes
Contains glycerine	yes	yes	yes
Contains Cellulose thickeners	yes	yes	no
Contains Methylparaben	yes	yes	yes
Contains Propylparaben	yes	no	yes
Labeled Water soluble	yes	yes	yes
Labeled Non-staining	yes	yes	yes
Labeled Condom compatible	yes	yes	yes
Labeled Alcohol and Fragrance Free	yes	yes	no
Container Material	Plastic	Plastic	Plastic
Sterile	No	No	No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2000

Ms. Kathleen Hacku
Quality Assurance Manager
Sheffield Laboratories, Div. Faira Ltd.
170 Broad St.
New London, CT 06320

Re: K001077
Lubrigel Personal Lubricant
Dated: July 18, 2000
Received: July 24, 2000
Regulatory Class: II
21CFR 884.5300/Procode: 85 HIS
21CFR 880.6375/Procode: 85 MMS

Dear Ms. Hacku:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

[redacted]

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Device Name: Sheffield's LubriGel Personal Lubricant

Indications for Use:

LUBRIGEL is specially formulated to lubricate condoms, provide vaginal moisture, and ease the insertion of rectal thermometers, enemas, douches and tampons.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

David C. Segmon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K001077

use: Over the counter ✓